

# Inquiring Minds



News and notes from the Department of Clinical Investigation  
Walter Reed Army Medical Center  
Washington, D.C.

July 2002

## Congratulations to the Bailey K. Ashford Research Award Winners!

Congratulations to the winners of the 28<sup>th</sup> Annual Bailey K. Ashford Clinical and Laboratory Research Award. This year's winners are CPT Scott Brietzke (Resident, Otolaryngology/Head and Neck Surgery) and MAJ Andrew Bauer (Fellow, Pediatric Endocrinology).

The BKA is presented annually to the graduating trainees who have contributed the most significant research during their years of training at WRAMC. This year DCI received a record number of nominations and it was very challenging for our selection committee to determine the winners.

Finalists presented their major research findings at the BKA Symposium on 2 May in Joel Auditorium. The selection committee rated the symposium presenters, and then interviewed each finalist the following day with a winner from each category chosen.

The clinical research award winner, CPT Scott Brietzke, conducted research on snoring, which is primarily the result of an overly floppy soft palate. Snoring is a very widespread problem that affects millions of Americans, yet snoring treatments are either very painful, very expensive, or both. Dr. Brietzke devised the first dynamic model to measure palatal flutter snoring and analytically compared several surgeries.



### Congrats BKA Winners!

Dr. Brietzke formulated a new minimally invasive procedure to treat sleep disordered breathing - Injection Snoreplasty. In this procedure the soft palate is stiffened by the injection of a sclerotherapy agent, sodium tetradecyl sulfate (Sotradecol). Following a successful animal model study, Dr. Brietzke followed with a human clinical trial. Twenty-seven patients were

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## Next WRAMC Research Course Set for October 17

The next WRAMC Research Course, presented by the Department of Clinical Investigation, is scheduled for Thursday, 17 October 2002. This one-day course will be held from approximately 0800 to 1600 in Sanford Auditorium at the Uniformed Services University of the Health Sciences (USUHS) in Bethesda, MD.

The course is open to physicians, nurses, dentists, and other health care personnel who will conduct clinical, animal or laboratory research at WRAMC. The course consists of a full day of training, targeted to new investigators and to those who have not completed a Research Training Course and desire to start a research protocol. Completion of this course is required for all individuals wishing to serve as a Principal Investigator (PI) on a WRAMC research protocol and for Research Coordinators. The course is also highly encouraged for all personnel involved in research to include associate investigators, data analysts, etc.

The objective of this course is to educate WRAMC medical personnel on the ethical issues, current regulations, and design considerations in conducting

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## Clinical Investigators Form New Society

If you do clinical trials for pharmaceutical or device companies, how do you respond when you don't get paid on time, or you are being harassed by the CRO for enrollment? Are you frustrated about not being able to complain about the budgets, or the liability and risks of having to indemnify large companies for studies? And most importantly, do you sometimes have doubts about the ethics of study design and the protection of your human research subjects?

If we have hit a nerve, we want to invite you to join the Society of Principal Investigators, a non-profit 501c6 professional organization composed of physicians and others who conduct clinical research according to protocol. This is an international multi-specialty grassroots organization formed in 2000 for the express purpose of giving physicians a group voice in dealing with the government, sponsoring companies, and contract research organizations. It's not a union. It doesn't negotiate contracts. It is not a research network aimed at securing protocols for individuals. The Society of Principal Investigators is dedicated to the advancement of the education and ethical standards of investigators, protection of human research subjects, and to provide a structure for the investigators to exchange ideas on how this unorganized specialty should advance.

In its first year of operation, the Society has provided at no

additional cost, online courses in Human Subject Protection and ethics for investigators and coordinators through a collaborative effort with the University of Miami. We have CME planned and course work which may prepare you for certification as a Clinical researcher if your desire. Next year we will have our first annual meeting. We will plan on testimony at upcoming Congressional hearings which are slated to make huge changes in the environment of clinical research. Academics have a voice. CROs have a voice. Medical Directors of pharmaceutical companies have a voice. Your coordinators have a voice. You need one too.

Refer to our web page at <http://www.med-society.org/spi> for more information. Get on our e-mailing list by writing the executive Vice President, Bob Lanier MD at [drboblanier@askdrbob.com](mailto:drboblanier@askdrbob.com).

There were over 70,000 physicians who signed Federal form 1572 last year in the US alone. Together we can improve the process of clinical research and provide much needed balance to the industry and government.

Marty White MD Washington, President  
Paul Ratner MD San Antonio, President elect  
Bob Lanier MD Fort Worth, Executive Vice President

## Update on Exempt Research

Exempt research refers to research that can be performed without formal review and approval by the WRAMC Human Use Committee. Exempt research is defined in 45 CFR 46.101(b) and AR 40-38, Appendix B.

Examples of Exempt Research are:

- Retrospective chart reviews (de-identified records)
- Surveys that do not collect sensitive information
- Laboratory tests in pre-existing de-identified samples

Investigators are cautioned to not make an independent determination whether their project is Exempt. Investigators need to complete and submit to DCI a short Exempt application. The Application can be downloaded from the DCI website: [www.wramc.amedd.army.mil/departments/DCI/Downloads/\\_Protocol%20Templates/ExemptReview/ExemptReview.doc](http://www.wramc.amedd.army.mil/departments/DCI/Downloads/_Protocol%20Templates/ExemptReview/ExemptReview.doc).

If the proposal is found to qualify as Exempt, a letter granting Exempt status is generated and sent to the Principal Investigator.

If you are doing a single-patient case report that is only

observational in nature, then no Exempt application is needed. (Note: the old rule was a sample size less than 20 did not require an Exempt application - that rule is **NO LONGER VALID**.)

The DCI POC for Exempt research is Mrs. Vicki Miskovsky at (202) 782-7833 or [Vicki.Miskovsky@na.amedd.army.mil](mailto:Vicki.Miskovsky@na.amedd.army.mil).

### CITI Web Based Research Course Reminder

DCI would like to remind all current and potential Principle Investigators, Associate Investigators, and Research Coordinators that a new web based research course is now available. DCI has elected to use the Collaborative IRB Training Initiative (CITI) Human Subjects Research Education Module, which is operated and maintained by the University of Miami. For more information and to register for this course, see the DCI website.

# WRAMC Researchers Making Waves: Do Specialists Differ on Do-Not-Resuscitate Decisions?

In this section of the newsletter, DCI randomly picks a WRAMC department/service and profiles a recent article of interest by that department/service. This article profiles the Department of Medicine, Pulmonary & Critical Care Medicine Service.

Opinions regarding do-not resuscitate (DNR) decisions differ between individual physicians. A team from the WRAMC, Pulmonary and Critical Medicine Service, led by CPT William Kelly, M.D., completed this study\* to determine whether the strength of DNR recommendations varies with medical specialty and years of experience.

Physicians at WRAMC were separated into the following groups: pulmonary and critical-care medicine; cardiology (PCCM); internal medicine; gastroenterology; hematology/oncology; infectious disease; and medicine house staff. The physicians were then invited to complete a study questionnaire consisting of 20 clinical summaries of patients who had been treated at WRAMC. Each physician was instructed to consider him/herself as the attending physician and to decide whether or not to advocate a DNR order and to quantify the strength of their opinion (1 for most strongly opposed to 10 for most strongly in favor of DNR order). Reasons for their opinions and demographic data also were recorded.

Out of the 115 physicians that responded, PCCM physicians more strongly recommended DNR orders than cardiologists, house staff, and general internists and were more inclined toward recommending DNR orders for more of the 20 patients compared to cardiologists. There were no differences between PCCM physicians and hematology/oncology, infectious disease, and gastroenterology specialists.

Dr. Kelly believes "the pulmonary/critical care medicine PCCM physicians may have had higher DNR scores (= more strongly recommended DNR) because of their comfort in discussing end of life issues or their knowledge about critical illness outcomes. Alternatively they may just be wearied from frequent exposure to death and its preceding suffering. Our observations do not prove any causation, but they have generated many interesting hypotheses."

With the house staff, the probability of recommending a DNR order correlated considerably with increasing years of experience with the opposite trend present in the specialty staff groups. Dr Kelly found no significant differences in opinion by gender, religion, or personal experiences.

The reasons given for recommending a DNR order were mostly that attempted resuscitation would be unsuccessful or were associated with a very poor outcome. The two most common reasons for recommending against a DNR were that the patient was unlikely to arrest during this

hospitalization and that the physician was unfamiliar with the patient's prognosis.

Dr. Kelly concluded that the strength of DNR order recommendations varies with medicine specialty and years of training and experience. An awareness of these differences and the determination of the reasons behind them may help to target educational interventions and to ensure effective collaboration with colleagues and communication with patients.

Dr. Kelly noted that some of the results were surprising. "Pulmonary/CAM journals do have 7-19 times more end-of-life articles than other medicine specialty core journals. Also, review of the literature shows that cardiologists are less likely to limit care-- this may reflect good outcomes with interventions or their patient population among other reasons. Studies have also shown biases against different diseases perhaps due to inaccurate prognostic assumptions."

Dr. Kelly also stated "the results show that the strength of a recommendation for a Do-Not-Resuscitate (DNR) order-- in other words a willingness to limit care-- is associated with internal medicine subspecialty and level of graduate medical education training. Care of our patients is multidisciplinary and often involves transfer from one service to another, especially at the end of life. Awareness of differences may help improve collaboration with colleagues and communication with patients."

\*Kelly WF, Eliasson AH, Stocker DJ, Hnatiuk OW. **Do specialists differ on do-not-resuscitate decisions?** *Chest* 2002 Mar;121(3):957-63.

**DCI is SHARPP..**

**Striving to**

**Help**

**All**

**Researchers from**

**Planning to**

**Publication**

## FAQs Regarding Submitting an Addendum

Considering modifying your existing WRAMC approved protocol? Not sure if you need to submit an addendum or write a new research protocol? This article hopes to clarify any questions/concerns that a principal investigator (PI) may have in reference to submitting an addendum.

### What changes to an approved WRAMC protocol require an addendum?

Addenda to research protocols are required for any of the following:

- Extension of approved studies to undertake new experiments.
- Additional funding to complete approved studies.
- Modifications in the use of human subjects or animals.
- Additional human subjects (or animals) to be enrolled.
- Modifications of the consent form.

In comparison, new research protocols are required for any of the following changes:

- Significant changes in research objectives.
- Major changes in procedure, method, or organization of the study, to include multi-year extensions of ongoing studies.
- Major changes in the use of experimental human subjects or animals.
- Projects ongoing for more than 5 years, unless the application of "Exception to DCI Policy" is granted by the Human Use Committee/Clinical Investigation Committee.

### How do I submit an addendum?

To obtain the specific guidelines on when and how to

submit an addendum to an existing protocol, refer to the addendum template ("addendum.doc") which can be found on the DCI website. In submitting an addendum, REMEMBER TO: 1) include a copy of the most recent Annual Progress Report (APR) and 2) attach an original and highlighted copy of the revised consent form. The documents are then submitted to Michelle Porter, DCI Protocol Coordinator, RRS, Bldg 6, Rm 4037.

### What is the review and approval process for my addendum?

Addenda with simple administrative changes or with minor changes to the plan that do not alter the risk to benefit ratio of the study can be approved administratively by DCI. Addenda requesting significant changes in the protocol, or any changes that may alter the risk or benefit to a study subject are scheduled for review at the next CIC or HUC meeting as appropriate. No changes in the protocol can be initiated until the addendum has been approved. Once the addendum is approved, a memo and stamped new consent form, if applicable, will be sent to the PI and the revised study can be conducted. Copies of the newly-stamped consent form must be used for all subsequently enrolled subjects. A copy of the HUC minutes will also be forwarded to the PI. Be sure to place all documents received in the Protocol Administrative Binder.

### Who is the point of contact for addenda?

Michelle Porter at (202) 782-7861 or [michelle.porter@na.amedd.army.mil](mailto:michelle.porter@na.amedd.army.mil).

## Research Alert List Reminder!

In order to provide better service to Walter Reed researchers, DCI has established a Researcher Alert List.

The Researcher Alert List consists of important periodic updates on policy changes, procedures, regulations, etc. that directly impact Walter Reed medical researchers.

For example, DCI has been receiving a record number of new protocols in the past two months, and has made a number of changes to assure these protocols are reviewed in a timely manner. We will be announcing these changes on the Researcher Alert List shortly.

If you are a Principal Investigator, Associate Investigator, research nurse, or want to be kept informed of key research developments, it is important that you be included on this list.

In order to receive the Research Alerts, e-mail Mr. Terrell Hunt at [Terrell.hunt@na.amedd.army.mil](mailto:Terrell.hunt@na.amedd.army.mil), and request to be added to the Research Alert list.

## 17 October WRAMC Research Course (cont. from page 1)

medical research.

Topics for this course include: an overview of DCI and resources available to investigators; elements on obtaining informed consent; commonly-made mistakes in protocol applications and how to avoid them; scientific misconduct; tissue banking; and publication issues. Certificates will be given at the completion of the sessions.

Registration will be available on the DCI web page or by calling Mr. Dan Rosen at (202) 782-6389. There is no registration fee for active duty military or Walter Reed civilian investigators. For further information on the 17 October Research Course, see the DCI website.



## Congratulations to the 2002 BKA Winners (from page 1)

enrolled and followed closely with sleep studies and clinical exams. A single, midline palatal injection was made in the submucosal plane, with the injected area turning purple as the agent takes affect. The scarring process is complete in about 4 to 6 weeks. Since the stiffened palate does not flutter as easily, snoring is reduced. If needed, second injections are made in the lateral areas of the palate.

The results were that twenty-five (92%) of twenty-seven patients reported a significant decrease in snoring with no post-injection complications. Based upon animal studies and a human trial, Dr. Brietzke has shown Injection Snoreplasty to be a simple, safe, and effective office treatment for primary snoring. Advantages over current snoring procedures include simplicity, low cost, decreased post-treatment pain, and minimal/no convalescence. His work has been published in the *Otolaryngology/Head and Neck Surgery* (Vol 124, May 2001, pages 503-510). Additionally, his work has been featured on multiple national and international television, radio, and newspaper interviews.

The laboratory research award winner, MAJ Andrew Bauer, conducted research on the biology of thyroid carcinoma of children and adolescents. Thyroid cancer is the most common endocrine cancer of children, yet there is little understanding of the pathogenesis and optimal treatment.

MAJ Bauer hypothesized there might be specific mutations that would account for the differences in clinical behavior among these tumors. To investigate this question, Dr. Bauer utilized the technique of comparative genomic hybridization (CGH) in which the entire human genome is evaluated at one time for regions of chromosomal gain or loss. Dr. Bauer identified specific regions of chromosome 20 (gain) and chromosome 13 (loss) that were altered in invasive papillary thyroid carcinoma. These findings are unique and provide the very first insight into regions of specific chromosomes that might be important in more invasive cancer phenotypes. Particularly important candidate genes in the amplified region of chromosome 20 encode matrix metalloproteinase (MMP) 9 and MMP 24. The MMPs digest the intercellular matrix and facilitate cell migration.

This link between abnormal CGH, cell migration, and invasive clinical phenotype is particularly important for the understanding of thyroid cancer progression. As a direct outgrowth of this work, Dr. Bauer postulated that the control of thyroid cancer invasion could be exploited as a novel treatment of anaplastic thyroid carcinoma (a disease with no currently effective treatment). A nude mouse xenograft model was then developed with which to examine the effect of matrix metalloproteinase inhibitors and angiogenesis inhibitors on the growth and metastasis of thyroid carcinoma. This data showed that vascular endothelial growth factor monoclonal antibody (VEGF-MAb) decreased tumor growth (56%) and was associated with increased expression of VEGF as well as the tumor suppressor protein, p53. Both of these molecular

observations are found in hypoxic tissues, supporting the hypothesis that VEGF-MAb inhibits tumor neovascularization, leading to tissue hypoxia and growth failure.

These findings are important because they provide the first insights into the nature of the chromosomal and vascular events which control thyroid cancer behavior. Dr. Bauer's work has earned him the *Fellow Thyroid Research Award* from the Endocrine Society with the manuscript for this work in press, *Cancer Genetics and Cyto genetics*.

The other finalists for this year's award were: CPT Christopher Cote (Resident, Otolaryngology/Head and Neck Surgery); CPT Peter Dunaway (Fellow, Gastroenterology Service); MAJ Edmond Paquette (Resident, Urology Service); MAJ Benjamin Starnes (Fellow, Vascular Surgery Service); MAJ E. Darrin Cox (Resident, General Surgery Service); CPT Bryan Fisk (Resident, Internal Medicine Service); and CPT(P) Joseph Flynn (Fellow, Hematology-Oncology Service).

All finalists were presented with an Army Commendation Medal, with the award winners (one from each category) presented with an engraved medallion and a \$750 prize at the WRAMC-NNMC graduation ceremony on 14 June.

A poster session was also included as part of the symposium to feature some of the exceptional research achievements of our graduating residents and fellows. A \$150 prize was presented to the winners that displayed the best poster presentation (one from each category). The winners for this year's poster session are CPT A. Hiroshi Andrews (Resident, Internal Medicine) for clinical research and LT David Allen, USNR (Fellow, Nephrology) for laboratory research.

DCI would like to congratulate not only the winners, but also all those nominated for this year's award. The work of these investigators represents some of the most exemplary research done at WRAMC over the past several years.

### "Investigator 101" CD-ROM Now Available

The **Investigator 101 CD-ROM** was produced by the Public Responsibility in Medicine and Research (PRIM&R) organization and provides education on the responsible conduct of human research and protection of human subjects. The course contains two presentations, Part 1: "The History and Ethics of Human Subject Research", with Dr. Jeffrey Cooper (Chair, IRB Albany Medical Center), and Part 2: "The Top 10 Responsibilities of Investigators", with Ms. Ada Sue Selwitz (Office of Research Integrity, University of Kentucky). Both talks are divided into short modules. Written transcripts of the talks and a comprehensive set of hyper-linked references and reading materials are also available. For more information on the CD-Rom see: [www.primr.org/101cdrom.html](http://www.primr.org/101cdrom.html).

Copies of the CD-ROM are available to WRAMC researchers at no charge. For your free copy, please call DCI at 782-6389. Click on "Sessions" to begin the training.

## Recent WRAMC publications

Congratulations to the following WRAMC investigators on their recently published papers. This list was compiled from a recent MEDLINE search of the literature. Listed articles have been cleared through DCI and the WRAMC Public Affairs Office. If you have recently published, and we have not included your publication, please let us know so we may list your publication in the next issue of the newsletter.

Alkins SA, Hurwitz KM, Sierra A. **Effect of Driving Pressure and Nebulizer Model on Aerosol Output during Intermittent Delivery with a Dosimeter.** *J Aerosol Med.* 2002 Spring;15(1):1-6.

Starnes BW, O'Donnell SD, Gillespie DL, Goff JM, Rosa P, Rich NM. **Endovascular Management of Renal Ischemia in a Patient with Acute Aortic Dissection and Renovascular Hypertension.** *Ann Vasc Surg.* 2002 Apr 18

Brown CG, Yoder LH. Stomatitis: An Overview: **Protecting the oral cavity during cancer treatment.** *Am J Nurs.* 2002Apr;102 Suppl4:20-3.

Shorr AF, Thomas SJ, Alkins SA, Fitzpatrick TM, Ling GS. **D-dimer correlates with proinflammatory cytokine levels and outcomes in critically ill patients.** *Chest.* 2002 Apr;121(4):1262-8.

Lehman RA Jr, Kuklo TR, Belmont PJ Jr, Andersen RC, Polly DW Jr. **Advantage of pedicle screw fixation directed into the apex of the sacral promontory over bicortical fixation: a biomechanical analysis.** *Spine.* 2002Apr15;27(8):806-11.

Stocker DJ, Foster SS, Solomon BL, Shriver CD, Burch HB. **Thyroid cancer yield in patients with graves' disease selected for surgery on the basis of cold scintiscan defects.** *Thyroid.* 2002 Apr;12(4):305-11.

Moncur JT, Lacy BE, Longnecker DS. **Mixed acinar-endocrine carcinoma arising in the ampulla of Vater.** *Hum Pathol.* 2002 Apr;33(4):449-51.

Jackson WL Jr, Shorr AF. **Vasopressin and cardiac performance.** *Chest.* 2002 May;121(5):1723-4.

Abbott KC, Agodoa LY. **Hospitalizations for Bacterial Endocarditis after Initiation of Chronic Dialysis in the United States.** *Nephron.* 2002 Jun;91(2):203-209.

Norton SA, Lyons C. **Blister beetles and the ten plagues.** *Lancet.* 2002 Jun 1;359(9321):1950.

Buckenmaier CC 3rd, Xenos JS, Nilsen SM. **Lumbar plexus block with perineural catheter and sciatic nerve block for total hip arthroplasty.** *J Arthroplasty.* 2002 Jun;17(4):499-502.

Grace KA, Swiecki J, Hyatt R, Gibbs H, Jones DL, Sheikh M, Spain J, Maneval KW, Viola R, Taylor AJ. **Implementation of a therapeutic-interchange clinic for HMG-CoA reductase inhibitors.** *Am J Health Syst Pharm.* 2002 Jun 1;59(11):1077-82.

Mitchell JP, Enyedy EJ, Nambiar MP, Lees A, Tsokos GC. **Engagement of complement receptor 2 on the surface of B cells from patients with systemic lupus erythematosus contributes to the increased responsiveness to antigen stimulation.** *Lupus.* 2002;11(5):299-303.

## Changes for WRAMC Research Policies & Protocol Template

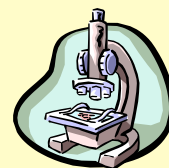
The Department of Clinical Investigation periodically updates our research policies and protocol templates, which are found in the "Download Protocol Templates" section of our website.

These are the files that have recently been updated:

- PI Guide -- New information on Exempt protocols
- Adverse Events - Policies have been clarified
- Human.doc - Sections on Medical Monitor and Adverse Events have been clarified
- Change of Medical Monitor - New form to use if your study has a new Medical Monitor
- Publication Clearance (pub-clear.doc)
- Gene Therapy Research - several updates

Please note that policies and templates previously distributed at DCI Research courses are now out of date - please discard your old disk!

New research protocols continue to come in to DCI at a record-setting pace -- the Department of Clinical Investigation is committed to reviewing and approving these protocols in the most expeditious manner possible. We appreciate your continued patience and support of the Walter Reed research mission.



# Recently Approved Protocols at WRAMC

Congratulations to the following principal investigators on their recently approved protocols. The following protocols have been approved since last issue.

## **DENTAC**

MAJ Carl G. Tempel, DE      02-94001: The Effect of Platelet Rich Plasma on Postoperative Pain, Edema, and Ecchymosis in Cervicofacial Rhytidectomy: A Pilot Study

## **Department of Allergy-Immunology**

MAJ Rohit Katial, MC      02-33003: Comparing the Rate of Return of the Weal-and-Flare Responses in Skin Prick Testing to Both Histamine Control and Aeroallergens after Discontinuing Two Weeks of Therapeutic Daily Dose Fexofendadine

## **Department of Clinical Investigation**

COL Maria Sjogren, MC      02-92009: A Multicenter Double-Blinded Study in Non-Cirrhotic Patients with Chronic Hepatitis C Who Are Non-Responders to Prior Interferon Alfa of Interferon Alfa + Peginterferon Alfa-2a with Peginterferon Alfa-2a + Placebo

COL Maria Sjogren, MC      02-92010: A Phase III Open label Study to Evaluate the Safety and Efficacy of RU-8811, in Patients with Types 3 or 4 Non-Alcoholic Fatty Liver Disease (NAFL)

## **Department of Medicine**

### *Cardiology Service*

LTC Thomas A. Wiley, MC      02-12005: Ventricular Resynchronization Therapy Randomized Trial (VecToR)

### *Endocrinology Service*

COL Robert A. Vigersky, MC      02-13007: The Use of Heart Rate Variation to Determine the Prevalence and Prognostic Significance of Autonomic Neuropathy in Patients with Either Diabetes Mellitus or Cardiovascular Disease

CPT David Y. Gaitonde, MC      02-13008: Effect of A Single Intra-Articular Steroid Injection on Serum Glucose Levels in Patients with Type 2 Diabetes Mellitus

### *Gastroenterology Service*

CPT Brian P. Mulhall, MC      02-14009: The Clinical Impact of Gastroesophageal Reflux in Adult Patients with Obstructive Sleep Apnea

COL Roy K.H. Wong, MC      02-14010: A Multicenter, Double-Blind, Three-way Crossover Intraesophageal and Intragastric pH Study of Three Esomeprazole Treatment Regimens in Documented Barrett's Esophagus Patients

CPT Mark J. Cossentino, MC      02-14011: The Effect of Baclofen on Patients with Gastroesophageal Reflux and Normal Lower Esophageal Sphincter Pressures: A Randomized Prospective Study

MAJ Inku Hwang, MC      02-14011E: Cytokeratin 7/20- staining patterns and cellular proliferation in long-segment Barrett esophagus (LSBE), short-segment Barrett esophagus (SSBE), and endoscopically normal esophagogastric junction with specialized intestinal metaplasia (EGJ-SIM)

### *General Medicine*

SFC(P) David A. Lott, NCOIC      02-10010E: A Study of Soldiers Assigned to the Medical Holding Company, Walter Reed Army Medical Center Before and After September 11, 2001

### *Hematology-Oncology Service*

COL Joseph Drabick, MC      02-15016: CALGB 79806: Effects of Dietary Soy on Biomarkers of Prostate Cancer: A Prospective Phase II Study

### *Infectious Disease*

MAJ Mark M. Fukuda, MC      02-19002E: Specificity of a Rapid Quantitative Real-time PCR Diagnostic Assay Plasmodium falciparum and vivax malaria from Human Blood

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# Recently Approved Protocols at WRAMC (cont. from page 7)

## *Nephrology Service*

CPT James Maxwell, MC 02-11014E: Post Kidney Transplant Humoral Rejection: A Retrospective Study of Presenting Features and Response to UVUG - Banff Classification

## *Pulmonary & Critical Care Medicine Service*

CPT Melanie Guerrero, MC 01-17006: Delivery of High Concentrations of Inspired Oxygen Using Humidified Oxygen by Nasal Cannula (Vapotherm)

LTC Joseph M. Parker, MC 02-17011: Vocal Cord Dysfunction and Hyperventilation: Do They Coexist?

LTC Lisa K. Moores, MC 02-17006E: Retrospective Validation of Clinical Prediction Scores for Diagnosing Pulmonary Embolism

LTC Joseph M. Parker, MC 02-17016E: Clinical Characteristics of patients with vocal cord dysfunction at Walter Reed Army Medical Center and Tripler Army Medical Center

LTC Lawrence S. Lepler, MC 02-17018E: Computed Tomography vs Plain Chest Radiography As A Screening Tool For Bronchogenic Carcinoma - A Pilot Study To Assess Recruitment

COL Arn H. Eliasson, MC 02-17019E: Treatment of Air Hunger at End-of-Life

## **Department of Neurology**

CPT John P. Ney, MC 02-71006: Assessment of Long-Term Efficacy of Paravertebral Muscle Treatment with Botulinum Toxin A (BOTOX) for Chronic Low Back Pain

## **Department of Nursing**

CPT(P) Carlton Brown, AN 02-75014E: Implementation of A Stomatitis Assessment Tool for Blood and Marrow Stem Cell Transplantation Patients: A Research Utilization Project

## **Department of Obstetrics and Gynecology**

LTC Scott G. Rose, MC 02-43008: GOG 176-A Phase II Trial of Pulse Actinomycin-D as Salvage Therapy for Failed Low Risk Gestational Trophoblastic Neoplasia

MAJ Jerome L. Buller, MC 02-44007: RF BIO-An Injectable Microstimulator for the Treatment of Refractory Urge Urinary Incontinence in Women

LCDR John Elkas, MC, USNR 02-44020E: The Use of Telemedicine in Gynecology Oncology

LTC Mary Parker, MC 02-44021E: Impediments to Compliance with Scheduled Colposcopy Appointments

LCDR John Elkas, MC, USNR 02-44022E: Survival of Patients with Gynecologic Malignancies Treated Within the Military Health Care System

## **Department of Orthopaedics and Rehabilitation**

CPT Aman Dhawan, MC 02-24015: The Effects of Tibial Malrotation on Tibiotalar Joint Biomechanics of the Medial and Lateral Gutters (facets).

COL Kathleen A. McHale, MC 02-24016: Syndesmosis Fixation: The Biomechanical Effects of Three Versus Four Cortex Fixation

LTC Robin Amaker, SP 02-96010E: Pain Perceptions and Adaptations Among Walter Reed Army Medical Center Beneficiaries

CPT David Jensen, MC 02-96010E: Epidemiological analysis of injuries from Army Ten Miler, a three year retrospective review

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## Tri-Service Clinical Investigation Presentations Available Online

All presentations from the "14th Annual Tri-Service Clinical Investigation Symposium" (6-8 May 2002) are now available online. This annual conference is held in San Antonio, Texas and is sponsored by the U.S. Army Clinical Investigation Regulatory Office and the Henry M. Jackson Foundation for the Advancement of Military Medicine. This course serves as a venue for educating researchers and administrators responsible for overseeing and ensuring the ethical treatment of human research subjects enrolled in clinical research studies sponsored by the U.S. Army, Navy, and Air Force. To view these presentations, click on the link located on the DCI website.

## IRB Calendar

The following Institutional Review Board (IRB) meetings will be held in the months of July, August and September 2002:

### CLINICAL INVESTIGATION COMMITTEE (CIC):

09 July	20 August	24 September
23 July	10 September	

### HUMAN USE COMMITTEE (HUC):

16 July	13 August	17 September
30 July	27 August	
06 August	03 September	

### INSTITUTIONAL BIOSAFETY COMMITTEE (IBC):

12 September

All meetings will begin at 1300, except HUC meetings which will start at 1200. All meetings will be held in the fourth floor conference room, Building 6, WRAMC.

## Clinical Research Meetings & Conferences

Below is a list of meetings and conferences focusing on various aspects of clinical research. For more information, please see the specific website:

**30-31 July 02: Department of Health and Human Services Meeting of the National Human Research Protections Advisory Committee (NHRPAC).** The NHRPAC meetings address a wide spectrum of issues regarding research involving human subjects. Topics include: public bioethics, informed consent, decisional incapacity, research with vulnerable populations, and social & behavioral sciences. The meeting will be held at the Four Points Sheraton Hotel in downtown Washington, D.C. No registration is necessary. <http://ohrp.osophs.dhhs.gov/nhrpac/nhrpac.htm>

**15-16 August 02: Protecting Human Subjects: Safety, Welfare, & Privacy.** The conference is sponsored by the Office for Human Research Protections (OHRP) and the Fred Hutchinson Cancer Research Center and will be held in Seattle, WA. [www.fhcrc.org/admin/iro/events/](http://www.fhcrc.org/admin/iro/events/)

**19-20 August 02: Clinical Data Management.** This intermediate level training course is for those in clinical data management who wish to expand their understanding of the changing regulatory requirements. By attending this course, you will be able to meet the highest standards of data quality in the changing regulatory environment, implement 21 CFR Part 11 regulations using FDA's clinical systems guidance, and successfully validate legacy or commercial-off-the-shelf software. Utilize statistical tools for data validation to facilitate the identification and correction of data errors. The conference will be held in Chicago, IL. [www.pharmatraining.org/clindatamgmt/](http://www.pharmatraining.org/clindatamgmt/)

**12-14 September 02: Good Clinical Practices for Clinical Investigators Training Program.** This program provides intensive training to clinical investigators and their study staff on Good Clinical Practices, FDA regulations and ICH Guidelines in order to equip them with the appropriate tools to conduct cleaner, safer, more efficient clinical trials. This course is applicable to all clinical investigators, study coordinators, and IRB members. [www.acrpnet.org](http://www.acrpnet.org)

**18-20 September 02: Current Research Issues & Solutions: Human Subject Protections.** The conference is sponsored by the Office for Human Research Protections (OHRP) and the University of Oklahoma Health Sciences Center and will be held in Oklahoma City, OK. For more information, contact Gail Carter, Program Assistant, Division of Education, OHRP via e-mail to [gcarter@osophs.dhhs.gov](mailto:gcarter@osophs.dhhs.gov).

**PRIM&R Meetings:** Public Responsibility in Medicine and Research (PRIM&R) hosts a series of workshops throughout the year focusing on the advancement of research programs and to the consistent application of ethical precepts in both medicine and research. These conferences address a broad range of issues in biomedical and behavioral research, clinical practice, ethics, and the law. [www.primr.org/conferences.html](http://www.primr.org/conferences.html)

**National Human Research Protections Advisory Committee (NHRPAC) Meetings:** These meetings address a wide spectrum of issues regarding research involving human subjects and are scheduled on a quarterly basis. [ohrp.osophs.dhhs.gov/nhrpac/mtgs.htm](http://ohrp.osophs.dhhs.gov/nhrpac/mtgs.htm)

# Recently Approved Protocols at WRAMC (cont. from page 8)

## **Department of Pediatrics**

CPT Thomas G. Eccles, MC

02-65001d: The Role of Erythropoietin and Erythropoietin Receptor Expression in Thyroid Carcinoma

LCDR C. Collura-Burke, MC, USNR

02-65001E: Asthma Education and Its Effect on Quality of Life

COL Gary Francis, MC

02-65001e: The Role of Insulin-Like Growth Factors in Thyroid Cancer

## **Department of Preventive Medicine**

Edward Wolfgang

02-35001E: The Lack of Disease Reporting at One Military Treatment Facility

## **Department of Psychiatry**

COL Ryo Sook Chun, MC

02-71002: Evaluation of the Effect of a WEB-BASED Automated Mental Health Intake System on Parent/Guardian Satisfaction and Discussion Providers' Response

Harold J. Wain, Ph.D.

02-72003: A Demonstration Project: Description of Well-Being and Satisfaction in Subjects Assigned to Follow-up Psychiatric Treatment in the Traditional Approach Vs. a Telemedicine Approach

LTC Dale Levandowski, MC

02-72009E: Prescribing trends of psychotropic medications in children and adolescents in a military health care facility

## **Department of Psychology**

CPT Marc A. Cooper, MC

02-73005E: Mental Health Diagnoses and Health Care Utilization in the U.S. Military: Detailed analysis of Defense Medical Surveillance Data

## **Department of Radiology**

MAJ Robert Bridwell, MC

02-45004: IM-D-CEA-C14 Pharmacokinetic and Biodistribution of Multiple Administration of CEA-Scan (Arcitumomab) Following Complete Resection of Primary Colorectal Carcinoma

## **Department of Surgery**

*Army Audiology & Speech Center*

Mary T. Cord, M.A. DAC

02-25005: Relationship Between Laboratory Measures of Directional Advantage and Everyday Success with Directional Microphone Hearing Aids - A Pilot Study

Van Summers, Ph.D

02-2565b: Effects of Presentation Level on Recognition of Low and High-Frequency Speech

LCDR Jose E. Sanchez, MC, USNR

02-25002E: Endoscopic Skull Base Surgery: An Integrated Approach

*Otolaryngology-Head & Neck Service*

LTC Anthony A. Bentley, MC

02-32006: Surgical Correction of the Incompetent Nasal Valve - A Rhonometric Analysis

*Peripheral Vascular Surgery Service*

CPT Matthew Wakefield, MC

02-21001E: Re-evaluation of carotid duplex for visual complaints: who really needs to be studied?

*Urology Service*

COL David G. McLeod, MC

02-28008: A Randomized, Double-Blind, Placebo-Controlled Phase III Clinical Trial Evaluating DCVax<sup>TM</sup> Prostate Autologous Dendritic Cells Loaded with Recombinant Prostate Specific Membrane Antigen (rPSMA) for the Treatment of Metastatic Hormone Refractory Prostate

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## Attention DCI Employees! Don't Forget Your BMAR!

All DCI personnel must be up to date in their BMAR training. BMAR on-line is available at:

[WWW.CMECOURSES.COM/DOD](http://WWW.CMECOURSES.COM/DOD)

Login is the first four(4) letters of last name and the password is the last five(5) numbers of your SSN. The BMAR course assignments will appear under the **My Course** tab. To take a course, simply click on the course link. To receive credit for a course you must complete all twenty-two(22) modules. As you complete each course, the course link will be removed from the **My Course** link and added to the **My Transcript** link. The online BMAR takes approximately 2½ - 3 hours to complete, with a test at the end to test your knowledge of the covered material.

DCI personnel are reminded to print off their evaluation sheets after they complete the training. These sheets certify that you have completed the course.

BMAR is still given didactically. The next didactic versions of BMAR will be given on 10 & 24 July, 07 & 21 August, and 04 & 18 September. All BMAR sessions are from 0730-1245 in Joel Auditorium, Bldg 2.

The following DCI personnel have birthdays in the months of July, August and September:

Janet Kapur (04 July)  
Vicki Miskovsky (13 July)  
Deborah Kessler (22 August)  
Jessie Martin (24 August)  
Elena Morris (28 August)  
Melanie Oringer (31 August)  
Greg Rose (01 September)  
Diarmuid Nicholson (09 September)  
Guy Durant (14 September)  
Robin Howard (16 September)  
Edward Bartlett (20 September)



## Recently Approved Protocols at WRAMC (cont. from page 10)

### Deployment Health Clinical Center

LTC Charles C Engel, MC

02-89005: Use of Focus Groups to Develop Background Information in Support of Health-e VOICE: A Web-Based Clinical Risk Communication Distance-Learning Tool

### Outside

MAJ Lance Raney, MC

02-81002: Evaluation of Problem-Knowledge Couplers in the Military Health System

CPT Aaron Saguil, MC

02-83002E: The Role of Research in Influencing the Discussion of Spiritual Beliefs and Practices with Family Practice Patients

CPT Aaron Saguil, MC

02-83003E: Travel Requirements of Physicians in Sports Medicine Fellowship Programs

### Telemedicine Directorate

COL Ronald Poropatich, MC

02-87002: User Needs Assessment and Usability Studies of Personal Digital Assistants (PDAs) in Clinical Practice

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Any submissions or questions about content should be directed to CPT Ken Capps at (202) 782-7823.

